

BI cont
reactant, which in turn, optionally via one or more additional reactants, has biospecific affinity to Reactant I.--

In the Claims:

Please cancel claims 5 and 7-10.

Please amend claims 1, 6, 11-17, 20, 21 and 24 to read as follows:

- Sub DI
1. (Twice Amended) A lateral flow method for the determination of an analyte in a sample involving utilizing biospecific affinity reactions, and comprising the following steps:
- forming a complex comprising:
Reactant I---Analyte'---Reactant*, where
 - Reactant* and Reactant I exhibit biospecific affinity to the analyte,
 - Reactant* is analytically detectable,
 - Analyte' is the analyte or an analyte-related reactant, and subsequently
 - determining a detectable signal from Reactant* in the complex (sample value), and
 - obtaining the amount of analyte in the sample by comparing the sample value with one or more calibrator values, each of which corresponds to a standard amount of analyte,
- wherein A) before determination of the calibrator value, either (i) calibrator or (ii) a binder for the calibrator has been bound to a matrix, and when a binder for the calibrator has been bound to the matrix, calibrator is added or calibrator predeposited in the matrix is released at the determination of calibrator value, and wherein the matrix is insoluble in the liquid medium in which binding of Reactant* to the calibrator occurs, B) the calibrator and the analyte have the ability to biospecifically bind to Reactant* via equivalent binding sites,
- b2

b2
D1
and C) one or more calibrator zones CZ comprising calibrator or binder for the calibrator are located in a single process flow stream with Reactant I in a detection zone (DZ).

6. (Twice Amended) The method according to claim 1, wherein

a. (i) each calibrator zone comprises calibrator in an amount corresponding to a standard amount of analyte, or

(ii) each calibrator zone contains calibrator binder, the amount of calibrator binder and the amount of calibrator corresponding to a standard amount of analyte, and

b. Reactant* is bound to the calibrator by transporting Reactant* through the calibrator zones.

sub
D2
11. (Twice Amended) The method according to claim 1, wherein along a single matrix is a flow matrix, and wherein along a single process flow stream, there are

a. one or more calibrator zones (CZ), each of which exhibits a matrix calibrator or a matrix calibrator binder,

b. one or more detection zones (DZ), none of which coincides with any calibrator zone, and in which a Capturer is firmly anchored and is either Reactant I or a biospecific affinity reactant, which directly or indirectly binds Reactant I biospecifically,

c. an application zone for Reactant*, $A_R \cdot Z$, which is located upstream of said CZ and DZ and to which Reactant* is optionally predeposited, and

d. an application zone for sample ($A_S Z$) which is located

i. upstream of or coinciding with a detection zone,

ii. downstream or upstream of or coinciding with $A_R \cdot Z$ ($A_S Z / A_R \cdot Z$), or

iii. upstream of, downstream of or coinciding with a calibrator zone,

DZ
cont

wherein the zone of application of sample ($A_S Z$) is located upstream of both detection and calibrator zones, and wherein Reactant* is added to $A_R Z$ if Reactant* is not predeposited, or buffer is added to $A_R Z$ if Reactant* is predeposited, and sample is added to $A_S Z$, optionally premixed with Reactant* if $A_S Z$ and $A_R Z$ coincide, such that analyte and Reactant* reach DZ at the same time, or such that analyte reaches DZ before Reactant*.

12. (Twice Amended) The method according to claim 11, wherein the calibrator zone or zones CZ exhibit a calibrator binder, and calibrator is predeposited upstream of the calibrator zone or zones.

13. (Twice Amended) The method according to claim 11, wherein the process flow stream comprises two or more of said calibrator zones.

14. (Twice Amended) The method according to claim 11, wherein the process flow stream comprises one or two of said calibrator zones, and the level of analyte in the sample is obtained by:

- a. having access to one or more separately obtained calibrator values, and
 - b. comparing a calibrator value for a calibrator zone (Positive Internal Calibrator = PIC), located in the process flow stream including the detection zone, with one or more of the separately obtained calibrator values,
 - c. adapting the measurement signal from the detection zone to the deviation of the measurement signal for PIC from the separate calibrator values, and subsequently obtaining the level of analyte in the sample by comparing the adapted measurement signal from the detection zone with one or more of the separately obtained calibrator values.
- b4

Sub D3
15. (Twice Amended) The method according to claim 11, wherein

a. $A_S Z$ is (i) common to $A_R \cdot Z$, forming a common zone ($= A_S Z / A_R \cdot Z$) or (ii) is located upstream of $A_R \cdot Z$, and

b. for alternative (i) sample is premixed with Reactant* before it is added to the common zone $A_S Z / A_R \cdot Z$, or sample is added to the common zone $A_S Z / A_R \cdot Z$ containing predeposited Reactant*, and for alternative (ii), sample is added to $A_S Z$, which is located upstream of $A_R \cdot Z$ which in turn comprises predeposited Reactant*.

16. (Twice Amended) The method according to claim 6, wherein Reactant* has particles as an analytically detectable group, and/or calibrator or calibrator binder is/are anchored to the matrix by particles.

17. (Twice Amended) The method according to claim 1, wherein the analyte is an antibody directed to Reactant I or to Reactant*, and

a. Reactant* is an antibody directed to the analyte and Reactant I is an antigen or hapten, when the analyte is an antibody directed to Reactant I, or

b. Reactant* is an antigen or a hapten and Reactant I is an antibody directed to the analyte, when the analyte is an antibody directed to Reactant*.

Sub D4
20. (Twice Amended) A device for transforming measured signal values of a complexed, analytically detectable reactant ($= \text{Reactant}^*$) to real amounts of analyte in a sample, in connection with performing an analysis method which utilizes biospecific affinity reactions for the determination of the amount of analyte in a sample, to form complexes comprising Reactant* in an amount which is related to the amount of analyte in the sample, wherein the device exhibits:

br

a flow matrix in which there is an area of process flow for the transport of Reactant*, and wherein there are in said area

- i. one or more calibrator zones (CZ) comprising a calibrator, or binder for the calibrator, which is firmly anchored to the matrix, the amounts of calibrator or calibrator binder, respectively, being different for at least two calibrator zones when at least two calibrator zones are present, and the calibrator exhibiting binding sites to which Reactant* binds, when Reactant* is transported through a calibrator zone,
- ii. an application zone for Reactant* ($A_R \cdot Z$) upstream of said one or more calibrator zones, and
- iii. one or more detection zones (DZ) downstream of said one or more calibrator zones.

21. (Twice Amended) The device according to claim 20, wherein a calibrator binder is firmly anchored in the matrix and the device comprises calibrator predeposited upstream of the calibrator zone.

24. (Twice Amended) The device according to claim 23, wherein $A_R \cdot Z$ is located upstream of or downstream of or coincides with $A_S Z$.

In the Abstract:

Please insert the following abstract subsequent to the claims of the application: